Registration Division Accomplishments FY2018

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The Registration Division (RD) of the Office of Pesticide Programs fulfills its mission to protect public health and the environment by using the best science and regulatory approaches in the registration of conventional pesticide products, authorization of emergency exemptions and approval of inert ingredients.

RD has developed the following Fiscal Year Work Plan. This Plan covers a wide range of topics and lays the goals for the division. This work plan rolls up to the OPP-wide work plan and provides a detailed listing of specific accomplishments for which RD has the lead as well as other projects jointly managed with other OPP divisions.

REGULATORY DECISIONS - COUNTS BY QUARTER FOR FY18

Activity	1st Quarter		2nd Quarter		3rd Quarter		4th Quarter		Total	
PRIA	Est./	Done	Est./	Done	Est./	Done	Est./	Done	Est./	Done
New Chemicals	2 /	0	0 /	1	2 /	1	1 /	3	5 /	5
New Uses for Existing Chemicals	75 /	23	75 /	31	75 /	58	75 /	39	150 /	151
New Product Registrations and Label Amendments	160 /	196	160 /	191	160 /	187	160 /	192	640 /	766
Non-PRIA	Est./	Done	Est./	Done	Est./	Done	Est./	Done	Est./	Done
Fast Track Label Amendments	280 /	270	280 /	311	280 /	259	280 /	227	1120 /	1067
Notification of Label Changes	295 /	369	295 /	258	295 /	185	295 /	357	1180 /	1169
Minor Formulation Amendments	na /	65	na /	48	na /	50	na /	65	na /	228
Emergency Uses	Est./	Done	Est./	Done	Est./	Done	Est./	Done	Est./	Done
Emergency Uses of Unregistered Pesticides (Sec. 18 Emergency Exemptions)	25 /	5	35 /	32	25 /	60	25 /	14	100 /	111
Inert Ingredients	Est./	Done	Est./	Done	Est./	Done	Est./	Done	Est./	Done
Food Use	5 /	6	5 /	4	5 /	4	5 /	8	20 /	22
Non-Food Use	5 /	4	5 /	5	5 /	2	5 /	6	20 /	17
RD Science Reviews	Est./	Done	Est./	Done	Est./	Done	Est./	Done	Est./	Done
Product Chemistry Reviews	225 /	239	225 /	233	225 /	269	225 /	217	900 /	958
Acute Toxicity Reviews	125 /	104	125 /	197	125 /	155	125 /	128	500 /	584
Efficacy Reviews	Est./	Done	Est./	Done	Est./	Done	Est./	Done	Est./	Done
PRIA Efficacy Reviews	40 /	21	40 /	26	40 /	15	40 /	20	160 /	82
NonPRIA Efficacy Reviews	10 /	13	10 /	3	10 /	1	10 /	1	40 /	18
Studies considered (MRIDs)		96		101		57		41		295
Registration Review and Product Reregistration	Est./	Done	Est./	Done	Est./	Done	Est./	Done	Est./	Done
Product Reregistration	42 /	10	43 /	24	42/	2	43/	4	170 /	40
Registration Review	50 /	0	60 /	4	70/	2	70/	5	250 /	11
Gold Seals (certifies a pesticide product is U.S. registered to facilitate export)	Est./	Done	Est./	Done	Est./	Done	Est./	Done	Est./	Done
Gold Seals	na /	95	na /	130	na /	133	na /	114	na /	472

Activity	1st Quarter		2nd Quarter		3rd Quarter		4th Quarter		To	
PRIA	Est./	Done	Est./	Done	Est./	Done	Est./	Done	Est./	Do
New Chemicals	2 /	2	0 /	1	2 /	1	1 /	3	5 /	
New Uses for Existing Chemicals	75 /	23	75 /	31	75 /	58	75 /	39	150 /	1
New Product Registrations and Label Amendments	160 /	196	160 /	191	160 /	187	160 /	192	640 /	7
Non-PRIA	Est./	Done	Est./	Done	Est./	Done	Est./	Done	Est./	Do
Fast Track Label Amendments	280 /	270	280 /	311	280 /	257	280 /	228	1120 /	10
Notification of Label Changes	295 /	369	295 /	258	295 /	183	295 /	357	1180 /	11
Minor Formulation Amendments	na /	65	na /	48	na /	50	na /	65	na /	2
Emergency Uses	Est./	Done	Est./	Done	Est./	Done	Est./	Done	Est./	Do
Emergency Uses of Unregistered Pesticides (Sec.18 Emergency Exemptions)	25 /	5	25 /	32	25 /	60	25 /	14	100 /	1
Inert Ingredients	Est./	Done	Est./	Done	Est./	Done	Est./	Done	Est./	Do
Food Use	5 /	6	5 /	4	5 /	4	5 /	4	20 /	
Non-Food Use	5 /	4	5 /	5	5 /	2	5 /	6	20 /	
RD Science Reviews	Est./	Done	Est./	Done	Est./	Done	Est./	Done	Est./	Do
Product Chemistry Reviews	225 /	289	225 /	283	225 /	269	225 /	216	900 /	9
Acute Toxicity Reviews	125 /	104	125 /	197	125 /	155	125 /	128	500 /	5
Efficacy Reviews	Est./	Done	Est./	Done	Est./	Done	Est./	Done	Est./	Do
PRIA Efficacy Reviews	40 /	21	40 /	26	40 /	15	40 /	20	160 /	
NonPRIA Efficacy Reviews	10 /	13	10 /	3	10 /	1	10 /	1	40 /	
Studies considered (MRIDs)		96		101		57		41		2
Registration Review and Product Reregistration	Est./	Done	Est./	Done	Est./	Done	Est./	Done	Est./	Do
Product Reregistration	42 /	10	43 /	24	42/	2	43/	4	170 /	
Registration Review	50 /	0	60 /	4	70/	2	70/	5	250 /	
Gold Seals (certifies a pesticide product is U.S. registered to facilitate export)	Est./	Done	Est./	Done	Est./	Done	Est./	Done	Est./	Do
Gold Seals	na /	95	na /	130	na /	133	na /	114	na /	4

REGULATORY DECISIONS

New Active Ingredients Completed in FY 18

- Flutianil: A new reduced risk fungicide registered for use on apples, cantaloupes, cherries, cucumbers, grapes, squash and strawberries. Flutianil is a new novel mode of action chemical that inhibits haustoria formation in powdery mildew fungi and thus inhibits fungal infections. It has a favorable human health and ecological profile.
- Pydiflumetofen: A new reduced risk fungicide registered for use on ornamentals, golf course turf, and multiple agricultural crops. Peanut growers are particularly excited about this chemical as for suppression of Scelerotina blight on peanuts. It has a favorable human health and ecological profile. The Agency reviewed this as a joint review submission with Canada.
- G77: A new herbicide/nitrogen fixer.
- Afidopyropen: A new insecticide with a favorable human health and ecological profile. Not acutely toxic to bees. Narrowly focused risk to aquatic invertebrates mitigated through label restrictions.
- Transfluthrin: A new insecticide proposed for use in killing mosquitoes, stable flies, and sand flies in certain enclosed and semi-enclosed areas. The end-use product is designed to meet the needs of the Department of Defense, which expressed a desire for a product that could be deployed in semi-permanent structures (e.g., large tents) and kill invading mosquitoes, stable flies, and sand flies for up to 21 days. It may also be used by the general population in areas such as recreational vehicles and outbuildings.

Import Tolerances Only

- Fenpicoxamid: Published October 16, 2017 – The U.S established tolerances without a U.S. registration in/on banana, rye, wheat grains for trade purposes. Fenpicoxamid is a new fungicide developed for use on bananas in Central and South America and on small grains in Europe.
- Triflumezopyrim: Published October 16, 2017 – The U.S. established an import tolerance for rice. This action was completed nearly two months before the PRIA due date.

New Uses

See Appendix B for full list of FY 18 completed New Uses.

New Use Highlights

- Flupyradifurone: A reduced risk insecticide registered for seed treatment of soybeans.
- Clethodim: New herbicide for use on multiple minor use crops (IR-4 submission).
- Sulfentrazone: New herbicide used to control broadleaf weeks in a wide variety of crops.
- Kasugamycin: New tolerances for the antibiotic, kasugamycin on the cherry subgroup and walnuts to control bacterial blast and suppression of bacterial canker in cherry and walnut blight in walnut production.

Public Participation Actions Other than New Actives

The following table includes registered chemicals subject to the public participation process. (*All new active ingredients automatically require Public Participation are listed separately in Appendix A*). To find in regulations.gov, search by public process for" and "name of chemical".

Registered Chemical (See Appendix A for new AIs)	Reason for Public Process	Type	Uses	PRIA Due	Branch
Kasugamycin	Significant new use	Antibiotic	Walnut, cherry	3/1/2018	FB
Pyrifluquinazon	First Food Use	Insecticide	Brassica, head and stem	5/22/2018	IBV2
Quizalifop	GMO	Herbicide	GMO corn	12/15/2017	HB

Emergency Exemptions and State Registrations (Special Local Needs)

Section 18s Projected and Completed Counts

- See Table 1.

Section 18 Major Issues

- Water purification tablets to address public health concerns in the wake of Hurricane Maria. This was a 1-year public health exemption for Puerto Rico.
- Quarantine exemption for bactericides to suppress citrus greening symptoms in California.
- Repeat quarantine exemption authorized to the United States Department of Agriculture's Animal and Plant Health Inspection Services for emergency readiness in the event of an outbreak of foot-and-mouth-disease, classical swine fever, or African swine fever.

Continuing Participation

- MUERB's Emergency Response Team continues to participate and lead through major roles in agency discussions, such as citrus greening control efforts; public health concerns; ensuring safety of emergency pesticide use in areas impacted by catastrophic events *(e.g.* hurricanes); finding tools against noxious pigweeds, aircraft disinsection issues (a major global public health effort); and on-going OPP antibiotic policy discussions.
- MUERB continues to heavily participate in the agency's deliberations on the various state-led efforts under FIFRA authorities, such as cannabis production involving potential pesticide usage, finding effective tools against bentgrass in Oregon, and providing guidance to Florida and inquiring states on aspects of antibiotic uses in agriculture.

Special Local Need Highlights

- Issued denial of State Special Local Need requests for pesticide uses on cannabis.

Continuing effort

- Electronic Portal for Section 24(c)s: RD initiated efforts to establish an electronic portal for section 24(c)s and section 18s to provide an avenue for applicants of the subject actions to

submit electronically versus through standard U.S. postal services or courier. Creating an electronic portal would minimize the number of actions returned due to address issues. More importantly, it would support the strategic goal "Rule of Law & Process – Streamline & Modernize and Improve Efficiency & Effectiveness" under the FY18-22 Transformation Strategy.

Other Projects / Outreach for Section 18s, Special Local Needs (24cs)

- Audit: RD worked on a response to the OIG Section 18 Audit.
- PREP: RD participated in the 2018 Registration and Re-evaluation course, as part of the Pesticide Regulatory Education Program (PREP) for state, territory and tribal program managers by presenting Section 18 and Section 24(c) procedures and practices to an audience of approximately 30 people.
- Workshops: RD hosted 24(c) workshops to reduce the 24(c) backlog of ~100 pending actions to less than 20 for 24(c)s pending since 2012 and earlier.
- Section 18 Webpage Update: RD, in collaboration with ITRMD, revised the Section 18 webpage to allow users to search on any of the available terms or combination of terms. Users can then manipulate the search data to personalize or download as needed. The database will be updated quarterly and contains the past 10 years of Section 18 actions.
- FOIA Request: RD provided 85 sulfoxaflor cotton and sorghum records (state Section 18 applications and authorization letters) to ITRMD in response to several on-going Section 18 FOIA requests.
- Section 18/24(c) ICR Consultation Questions: RD completed the 2018 FIFRA Section 18 and 24(c) consultation process. FEAD requested feedback from three state representatives: Maryland, Louisiana and Washington, to answer questions based on their assessment of burden estimates for Section 18 and 24(c) data reporting requirements, as detailed in the information collection request that published in the Federal Register on May 8, 2018.

Minor Uses

Completed Actions

- A total of 25 final tolerance rules were completed by minor use team, including 6 rules which weren't for IR4, but were done to help the other branches
- Clethodim was a particularly significant new use as herbicide for multiple minor use crops (IR-4 submission).

Other Projects

- Minor Use SOP: RD updated the minor use team leader in-processing SOP to prioritize public interest findings and changes based on current practices.
- Minor Use Tracking: RD developed a tracking document for minor use actions and shared it with HED branch chiefs to facilitate coordination between the divisions.
- Minor Use Joint Reviews/Workshares (2018): RD rejuvenated cooperation with Canada and California on joint reviews and workshares

- Minor Use Public Interest Finding/Mini-Stoplight Analysis: RD tightened up the public interest finding process and coordinated with IR4 to fill in some gaps for IR4 actions that had not been screened in previous stoplight analyses.

Recurring Activities

- Assist in the training of new PM team members on tolerance document writing, since it completes the majority of FRs for RD.
- Crop Grouping Update effort - in conjunction with FEAD and HED
- Publication of Proposed Rule for the establishment of Crop Groups 25 and 26.
- MRLs IT Pilot Program - in conjunction with HED
- Consultation with USDA's IR-4 with Food Use Workshop, prioritization of minor use residue trials, leading OPP's response to IR-4 through "red light/green light analysis" for IR-4 to consider in decision making processes.
- RD's semi-annual all-day venue for IR-4, Canada (PMRA), and California DPR to examine timelines, workload and policy concerns that address minor use and specialty crop issues, with broad participation from throughout OPP (e.g., HED, BEAD, EFED, and RD).
- Work with IR-4 to schedule annual IR-4 crop tour.
- Minor Use Joint Reviews/Workshares (2019): Continued cooperation with Canada and California on joint reviews and workshares.

Product Reregistration

Counts of Projected and Completed Actions

- See Table 1.

Inert Ingredients

Projected and Completed Inert Uses and Reviews

- See Table 1 for counts of completed Inert Food and Nonfood Uses, as well as Product Chemistry and Acute Toxicity Reviews
- Other Production for Inert Team
    - Participated in a workshop developed for registrants on exposure assessment for inert ingredients as requested by the PRIA coalition
    - After working closely with CLA CSF review committee and inert steering committee in developing criteria for classifying a chemical as a 'commodity chemical' and developing a draft list, the Inerts Team estimates project completion in Q3 FY18.
    - Working with ITRMD on transferring CSF scanning database, mixture database and ejacket need for CSFs (Q4 FY18)
- Ongoing Support for HED
    - Member on various HED committees such as HASPOC, CARC, RARC, sometime ROCKS, TOXSAC and consultation on dermal absorption

Registration Review

RD will conduct final label reviews for product labels received by PRD. After a preliminary label review to verify correct ID label mitigation language, the labels will be forwarded to RD for a complete label review and label processing. The schedule for RD's label reviews is dependent on PRD's schedule. RD will coordinate with PRD in this effort.

Labels Received FY18

- Paclobutrazol - Received 18 labels from PRD

?PRD Projected Labels for RD Review FY18

- Labels that might be received from PRD include labels with ID's reaching into Q2 FY18. This may include up to 65 conventional chemicals with roughly 2,500 registered products. PRD estimates as many as 300 labels to be forwarded to RD during FY18, including sulfonylurea (approximately 550 products requiring review for Registration Review label mitigation).

HIGH PROFILE REGULATORY ACTIONS

Critical Pest Situations

Citrus Greening/Asian Citrus Psyllid

RD will support grower response to pest management tools necessary to help manage citrus greening See also "High Profile Chemicals".

- Launch public process for oxytetracycline, kasugamycin - FY18, Q1-completed
- Kasugamycin registered - FY18, Q2-completed
- Registrant/IR-4 meeting on antibiotics to discuss regulatory positions - FY18, Q1-completed
- Kasugamycin applications in-house. Decision completed in Q2, FY18-completed
- Meet with applicants that have pending actions in-house -FY18, Q1-completed
- Meet with growers/researchers, out-reach with other extensions on antibiotic resistance-FY18, Q1-completed

Zika/Aedes spp.

RD will expedite any actions for mosquito control to support public health efforts related to the Zika virus. Emergency exemptions, new registrations and amendments are expected.

- Permethrin Disinsection Section 3 Product for DoD – FY18, Q3
- New dibrom formulation to assist in Hurricanes Harvey and Irma

Asian Carp Control

- RD along with EFED worked with the US Geological survey to discuss a path forward for CO2 use as a pesticide to limit the expansion of invasive Asian carp.

Argentine Ant Control in the Channel Islands

- Worked with the Nature Conservancy and registrant to find a solution to the Argentinian ant problem in the Channel Islands through an amended registration of thiamethoxam.

GMO Registrations

Support Final Decision of Enlist on 2,4-D-Toleranct Corn, Soybeans, and Cotton.

- Monitor and evaluate an crop damage incidents reported in 2018 growing season
- Collaboration with state regulatory partners to achieve meaningful regulatory changes for 2018 growing season in order to minimize off-target movement of dicamba and impact on sensitive crops. (on-going)

Regulatory Decision for Quizalifop on GE (carrying Enlist trait) Corn

- Completed the regulatory decision for quizalifop on quizalifop resistant corn
- Final decision and supporting documents issued

High Profile Chemicals

Antibiotics

PRIA actions – final regulatory plan and timeline for Section 3 products completed in Q3 FY18

- RD collaborated with our federal partners (FDA, CDC, and USDA) to address potential resistance issues for the use of antibiotics as pesticides.
  Contact: Cynthia Giles-Parker

Sulfoxaflor

Issued "New" Sulfoxaflor Registrations Following Court Decision Vacating the Original Registrations

- Worked with EFED to determine registration potential for selected pending uses that were vacated (Q1 FY18)
- Issued Section 18s for critical pests driving emergency situations (ex. cotton/Tarnished Plant Bug, sorghum/Sugarcane aphid, citrus/Citrus psyllid, alfalfa/Lygus)
  Contact: Meredith Laws

Anthraquinone

- Evaluated cancer classification rebuttal
- Removed time-limit on rice seed registration Q3FY18
  Contact: Gene Benbow

High Profile Label Changes

Agency-initiated label changes addressing risk issues.

Strategy to reduce Water Soluble Package misuse (Q1 FY18)

- Effect label changes consistent with intended exposure reduction strategy - ongoing, continuing from FY17. Registrants granted an extension to Q1 FY18 to submit label amendments
  Contact: Venus Eagle, IVB3

Revised Respirator language

- Revised Respirator Language: In collaboration with FEAD, RD completed training on new respirator language and began implementing label language requirements to improve worker protection.

Dicamba adverse effects

- In October 2017, RD approved label amendments for dicamba products for use on dicamba-tolerant cotton and soybeans, working throughout the year to support the new label implementation and training, including participation in several webinars with State Departments of Agriculture. RD collaborated with state regulators, university scientists, other Federal agencies, etc. on collecting data to better understand adverse effects seen in the field to prepare for a regulatory decision on the "over-the-top" registrations

Continuing effort

Dicamba crop-incident related label mitigation

- Collaborative work with state lead agencies (ongoing)
  Contact: Rueben Baris, HB

? Nano Ingredients

Nano inert ingredient

- RD will take public comment on the adequacy of the data we have required (Q2 FY18)

Insecticide containing nano inert

- Discuss policy implications of approval of these types of products. (Q1 FY18)
- Develop recommendations for path forward and approval of expanded label. (Q1 FY18)
  Contact: Kerry Leifer, CITAB

Pollinator Protection

Pollinator Protection Plans - Acute Risk Mitigation

OPP will continue to support state and tribes in the development and implementation of Pollinator Protection Plans. OPP will partner with states, tribes and stakeholders to further promote the plans and to continue to monitor and evaluate the effectiveness of the plans at mitigation risk to bees from pesticides and improving pollinator health.

- Finalized recommendations for performance metrics for consideration of the full PPDC

Continuing effort

OPP is continuing work to finalize its policy to mitigate acute risk to pollinators and effectuate the mitigation for new active ingredients that are acutely toxic. PRD will implement the policy for existing chemicals through Reg Review.

Synergy

- RD has supported EFED in the development of policy papers to determine OPP's position on the patents granted by US Patent & Trademark Office (PTO) and guidance for further consideration towards synergistic relationships between active ingredients

LITIGATION, PETITIONS, AUDITS, ECRs

Petitions with RD as Lead

RD completed the following petitions in FY18.

No	Subject of Petition	Petitioner & Related Statute(s)	OPP Divisions, OGC, and Contacts	Date Received	Comments
9	**ACETOCHLOR** Petition to deny acetochlor technical registration by Sharda Cropchem Ltd.	Acetochlor Registration Partnership (ARP) and Monsanto **FIFRA**	**RD** Sarah Meadows Reuben Baris **OGC** Ariadne Goerke **FEAD/PRSB** Branch Chief	March 17, 2017	Path forward will be a denial of the petition. Waiting for OGC lead.
13	**SERGEANTS PET CARE PRODUCTS** Petition to reject registration #91384-3 by **Cap IM** because they were never authorized to rely on exclusive use data owned by Sergeant's	Sergeant's Pet Care Products, Inc. (Deborah Chadbourne, Attorney for Sergeant's) **FIFRA**	**RD** Bo (Kable) Davis **OGC** Liz Thaler **FEAD/PRSB** Branch Chief	December 13, 2016	Awaiting draft petition response from Thaler (OGC).
16	**CLOTHIANIDIN** Suspend and cancel registrations of clothianidin (pollinator impacts)	Center for Food Safety, Beyond Pesticides and other groups and beekeepers **FIFRA**	**RD** Venus Eagle **OGC** Mark Dyner: Michele Knorr **FEAD/PRSB** Branch Chief	March 21, 2012	8/7/17: RD and OGC coordinating response
17	**COMPOUND 1080 (sodium fluoroacetate)** Petition to issue notice of intent to cancel and to suspend the registration	Animal Welfare Institute, Animal Legal Defense Fund, Center for Biological Diversity, Project Coyote, Predator Defense **FIFRA**	**RD** Venus Eagle **OGC** Amber Aranda Bob Perlis **FEAD/PRSB** Branch Chief	January 12, 2017	Response signed by OD on 12/12/17
22	**PHOSPHINE PRODUCERS ASSOCIATION** Petition to deny InTech Pharma application for me too product	Registrants of Phosphine Products FIFRA	**RD** **Venus Eagle**	11/3/2017	

Petitions with Other Lead, RD Support

OGC or EFED LEADS

- All transferred to FY19

Litigation

Friends of Animals v. Scott Pruitt

- Litigation challenges Humane Society's wild horse contraceptive IVB3
- RD has created the Administrative Record

Other Legal Issues (awaiting MJ edits)

Phostebupirim liquid formulation (actions moving to FY 19, but Marion providing changed language)

- EPA will issue 2-month extension of registration to allow for label mitigation and completion of CCA study protocol.
- Provided labels are submitted, additional extension expected to allow for study completion.

Contact: Marion Johnson, IVB2

Audits

IG Audits

Recurring Audits

- PRIA, FIFRA, Financial
- Product Reregistration

Enforcement Cases

- Region 9: Collaborated with Region 9 on an enforcement case concerning illegal imports of unregistered technical ingredients from China. Because of the collaboration, the registrant returned the shipment to China.
- Region 4: Worked with Region 4 on a denial of entry for 80,000 – 400,000 misbranded products from Germany.
- Expert Testimony: Provided expert testimony resulting in the conviction in an illegal pet spot-on case.
- Whistleblower: Two employees of a company notified USDA, FDA and EPA of potential contamination and misrepresentation in lab reports.

SCIENTIFIC TOOLS, POLICIES, GUIDANCE

Child Resistant Packaging (CRP)

Recurring Work

- RD leads the Child-Resistant Packaging team
- Reviews CRP submissions & answers registrant questions
- Will develop new guidance for certification
- Updates the CRP website
- Responsible for the CRP ICR

First Aid Labeling

RD completed this initiative completely, without carry-over into FY 19.

- Conference call with California on comments and agencies decision (Q1 FY18)-completed
- Address comments received (Q2 FY18)-completed
- Prepare response to comments document (Q2 FY18)-completed
- Brief DDs on comments and response (Q2 FY18)-completed
- Briefed DAA on comments and OPP decision (Q2 FY18) - completed
- Guidance posted in the Docket (Q2 FY18)- completed
- LRM update to link to the guidance (Q3 FY18)-completed
  RD Contact: Heather Garvie, FB

Pet Product Mitigation (RD, HED)

RD worked on Phase II Spot-On Mitigation and label consistency initiative, as well as Seresto incidents. Specific action items are carrying over to FY 19.

Phase II Spot-On Miigation
The intent of the Phase II Spot-On mitigation initiative is to facilitate the submission of enhanced reporting requirements using a template such that the data will be available to HED in a consistent and usable format for meaningful analysis of data.

- Webinar concluding Pet Spot-On Enhanced Reporting Pilot and Template Implementation.
- Initial communication with registrants regarding options for amending conditions for registration when using the recommended template.
- Received initial enhanced reporting data in standard template, and initiated reviews.

Enhanced Reporting Template

- Developed a template to collect enhanced reporting data for pet spot-on products and held a webinar to provide implementation support. Collection of data in a consistent format will improve the Agency's ability to evaluate safety of pet spot-on products.

Reduced Animal Testing

Recurring Work

- To support reduced animal testing, some *in vitro* eye and skin irritation studies are being submitted along with confirmatory *in vivo* eye and skin irritation studies as part of acute toxicity data submissions. These studies will ultimately provide the Agency with information regarding the potential suitability of the use of *in vitro* alternatives for skin and eye irritation studies.

Confidential Statement of Formula (CSF) Guidance

CITAB worked on End Use Product Clarification Guidance, Agency Letter regarding multiple dyes and fragrances, and a policy letter regarding sole use of basic registration numbers on CSFs for active ingredients. Specific actions have been carried over into FY19.

Minor Amendment/Notification/Non-Notification PRN (RD, AD, BPPD, FEAD)

Finalize draft document to update Pesticide Registration Notice (PRN) 98-10 with criteria for submitting requests under OPP's minor amendment/notification/non-notification program. Specific milestones have carried over into FY 19 workplan.

Efficacy

Efficacy Guidelines

RD has worked in FY 18 to update the various performance product guidelines to reflect current scientific standards and practices, and to add more detail and clarity for stakeholders, thus reducing experimental design questions to EPA efficacy reviewers. The end result will be significant efficiency gains for both internal and external stakeholders.

- Specific milestones worked on and still pending are addressed in RD's FY 19 workplan.

Product Performance Rule

Efficacy reviewers evaluate data using consistent product performance standards and require specific representative invertebrate test species for efficacy studies. To make these practices more transparent, they will be codified in a rule and published for the benefit of all stakeholders. This topic has already been taken to the Scientific Advisory Panel (SAP); future steps include working with FEAD to respond to SAP comments and to rewrite the rule in the proper format.

- Sought FIFRA Scientific Advisory Panel recommendations on two EPA test guidelines, one for red imported fire ants and one for premise treatments.
- Rule writing efforts are carrying over into FY 19 Workplan.

  RD Contact: Dr. Jennifer Saunders

Treated Fabric Registration Guidance

In an effort to increase consistency, the Registration Division (RD) Invertebrate-Vertebrate Branch 1 (IVB1) is developing draft guidance for the registration of impregnated (or treated) fabrics and associated consumer products. This guidance will assist external stakeholders is submitting new or amended product applications. It will also assist internal stakeholders in maintaining consistency.

- Milestones for this effort have transferred to RD's FY 19 workplan.

Human Studies Review Board (HSRB) (RD, OPP/IO)

OPP presents protocols and subsequent studies involving human subjects to the Human Studies Review Board for guidance and assurance that protocols/studies are acceptable from both an ethics and science standpoint. RD writes the science review and works with HED statisticians on stats issues. The IO Human Research Ethics Officer writes the ethics review. Both the science and ethics reviews are formally presented to the HSRB by the respective OPP reviewers.

RD received two treated clothing protocols that were reviewed by the HSRB this year:

- January 2018 - Bernier, Ulrich, (2017) Laboratory Evaluation of Bite Protection for Repellent-Impregnated Fabrics. Unpublished document prepared by Uli Bernier and sponsored by Pinebelt Processing, Inc., August 09, 2017. 211 p. (MRID 50360801) – review is available here: https://www.epa.gov/sites/production/files/2018-01/documents/a. epa science and ethics review of landis pinebelt protocol final 12-29-2017.pdf

- July 2018 - Laboratory evaluation of mosquito bite protection from permethrin-treated clothing after 0, 50, 75, and 100 washings. Unpublished document prepared by i2LResearch USA, Inc. and sponsored by Pulcra Chemicals, January 17, 2018. 47 p. (MRID 50555701) – review is available here: https://www.epa.gov/sites/production/files/2018-07/documents/1a. epa science and ethics review of pulcra protocol 6-25-18 final.pdf

- RD received a protocol for a "BugBling" product, but the registrant subsequently withdrew the action.

Contact: Dr. Jennifer Saunders, IVB1

PARTNERSHIPS, OUTREACH AND TRANSPARENCY WITH STAKEHOLDERS

International

Joint Reviews - new projects

- Presubmisison chemicals – S2399, Isotianil, BAS750F, Pyraziflumid, Tetraniliprole, DPX-Q8U80, Broflanilide, 8- hydroxyquinoline, Tavaborole
- New Active Ingredient: pethoxamid (Primary review scheduled to complete FY18 Q2)
- MRL harmonization - Increase efficiencies by focusing joint reviews on high value areas and eliminate work on low value/high cost areas.

Pilots

- **Joint Review -Improving Efficiency / Streamlining Process**

RD collaborated with PMRA to pilot a process for Joint Reviews that would continue to assure harmonized tolerances/MRLs, but would increase efficiency and timeliness of new active ingredient reviews and decisions.

- **Import tolerance**
  To determine feasibility of accepting residue reviews from other national authorities. RD and HED are working on a streamlined approach for reviewing other countries' completed reviews instead of the required residue data. There is not an accompanying domestic registration under this pilot.
  - Tebuconazole -DD2 pending agency review. Completion expected Q2, FY18 (FB)

WHO Product Performance Activities

WHO PQT VCPAG Workshop. Purpose: gather feedback from all stakeholders regarding the transition of review responsibility from WHOPES to the Prequalification Team and as such allow stakeholders to present on their thoughts about what dossier requirements should be.

Recurring Meeting

- Efficacy data submission requirements will be discussed; the resulting data will be reviewed in recurring meetings by the Vector Control Product expert review panel.

- *WHO Equivalency Panel*. Purpose: advise on WHO criteria, procedures and data requirements for determination of equivalence for public health pesticide products.
  - Vector Control Product expert review panel (ongoing)
  - JMPR meeting participation and review of fenpyroximate data set

Global Harmonization System Workgroup

Recurring Meetings

- Internal workgroup with US / European collaboration
- Addresses acute toxicity labeling; signal words and use of pictograms. Attempting to develop labeling that is understood across international borders to protect human health

PRIA 4 Registration Review Reporting Requirements

- PRIA 4 requires reporting on registration review decisions. PMs are tracking label mitigation for products under registration review following joint SOP developed by RD/PRD and located on Sharepoint.
- PMs were briefed and reminded to track mitigation decisions at the product level for Registration Review reporting
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Ongoing Activity

- RD/PRD joint review of labels underway
  RD Contact: Cynthia Giles-Parker, FB. IO Contact: Steve Schaible

State Partnership -- Dicamba

- Regulatory partnership with states to implement changes in dicamba registrations.

- Work with state partners to develop effective monitoring system for potential off-target damage for 2018 growing season.
- Revisit safety finding for over-the-top use of dicamba on GE soybeans and cotton. *(Oct. 2018)* *Contact: Dan Kenny, HB*

External Stakeholder Involvement

Brown Marmorated Stink Bug (BMSB)

Annual Meetings with External Stakeholders

- RD participates in a cross-Agency scientific advisory panel on control and new chemistries. Usually have 2-3 external meetings per year.

American Phytopathology Society (APS)

Recurring

- RD invests in continuous learning through external experts, such as APS liaison Wayne Wilcox, who made several Fungicide 101 presentations to help RD staff a better understand fungicides, disease, and control strategies, as well as providing expert analysis regarding claims on existing fungicide labels.
  Contact: FB, FHB

Weed Science Society of America Liaison

On-going Activity

- RD manages the WSSA liaison position, a highly successful program that it previously designed and implemented. This liaison program is now shared with BEAD, PRD and EFED. WSSA has played a significant role by sharing information with the Agency to better understand resistance management, spray drift, and synergy to name a few.
- Introduce and help develop new WSSA liaison (Greg Kruger, replacement for Mike Barrett). Help develop relationship building with other OPP colleagues, teach and monitor liaison policies, and oversee implementation of into liaison position.*Contact: Dan Kenny*

Federal Agencies

Armed Forces Pest Management Board

Recurring Meetings

- The EPA Liaison to the AFPMB provides guidance to DoD on OPP policy and procedures that may affect military pest management.
- The AFPMB typically meets twice per year in Silver Spring, MD. The EPA Liaison typically attends symposia devoted to bite protection, repellents, and pesticides.

Consumer Product Safety Commission

Recurring Meetings

- Cross-agency workgroup developed between EPA/OPP Registration Division and Antimicrobials Division with the CPSC to develop standard practices for Child Resistant Packaging and Senior Adult Packaging requirements.

- The team reviews inquiries and evaluation procedures from stakeholders to ensure compliance with 16 CFR 1700.20 (Poison Packaging Prevention Act) and 40 CFR Part 157.20-36 (FIFRA).
- Working toward an improved self-certification program for registrants
  Contact: Venus Eagle, IVB3

Food and Drug Administration

Regulation of sunscreen/insect repellent products

- FDA is mandated to complete a drug monograph by late 2019 for over-the-counter sunscreen products, including personal insect repellent/sunscreen combination products, with the proposed rule likely to be published in near future. This monograph will likely note that the combination products are not considered safe and effective, given a lack of data.
  - IVB1 has participated in discussions with FDA regarding these combination products, and provided input/comments on the FDA proposed rule.

EPA-FDA Jurisdiction Determinations

Ongoing RD Role

- RD is POC for Jurisdiction Determinations under draft EPA-FDA MOA.

Antibiotics

- **See** High Profile Chemicals.

Other Federal Interagency Communication

Ongoing Discussions

- CDC and FDA. Consulted both CDC and FDA on use of antibiotics and potential resistance from use of antibiotics and conazoles as pesticides. See Antibiotics discussion.
- USDA IR-4 program. Consulted with the IR-4 program on minor use petitions. See Minor Uses.
- Office of Emergency Management. Continued discussions on process improvement and coordination efforts for emergency situations that involve national security concerns (e.g., anthrax)

Trade Associations

Consumer Specialty Products Association

Quarterly, Recurring Meetings

- Quarterly meetings (Q1, Q2, Q3, Q4)
- The Registration Division meets with CSPA quarterly to discuss concerns, inconsistencies, and successful practices regarding the registration and review of efficacy data for consumer products. Past meetings have resulted in the development of the efficacy FAQ website, which addresses multiple efficacy related questions from CSPA.
  Contact:

Animal Health Institute

Biannual Meetings

- Biannual meetings to facilitate communication regarding staff changes, new policies, and ongoing initiatives concerning pet products (ongoing)

CropLife America and RISE

- Working in partnership with CropLife America and RISE, provided training and a forum for industry and government to discuss label challenges.

WORKPLACE IMPROVEMENTS TOWARDS A HIGH PERFORMING ORGANIZATION

RD Internal Initiatives

Decision Memo Template

- RD developed a new decision memo template for new active ingredients and new uses.

New Use/Minor Use Discussion Group

- RD undertook and effort to Identify unexploited efficiencies in the registration process for PRIA new uses. During FY18, RD actively pursued streamlining of FR documents, which will continue into FY19.
- See also the inter-Divisional effort regarding streamlined drinking water and eco assessments for PRIA new uses.

Product Manager Workgroup (PMWG)

Recurring Meetings

- RD PMs and Senior Regulatory Managers will continue bi-weekly meetings with minutes recorded to promote regulatory consistency within RD and provide an avenue for open dialogue, education, communication, and coordination among workgroup members.

SOPs and Training

To continue our process improvements and to further RD's goals of consistency in processing applications, we will continue in the development of SOPs

New Product SOP

- Confirm CITAB process change for acute tox reviews (Q1 FY18)
- Finalize and implement the new product SOP (Q1 FY18)
  Contact: Dr. Jennifer Saunders, Jennifer Gaines, IVB1

Bulletins Live 2 SOP

- Finalize and implement the BL2 SOP for me-too registrations (Q3)
  Contact: Gene Benbow, IVB2

RD Training Program (New Hires, et. al.)

Ongoing Activity

- The RD training team developed and maintains a training Sharepoint site (centralized location for staff to access OPP training presentations) for all staff in RD. This site provides information for on-boarding new staff, provides a supervisory toolkit and other important information for staff.
- The team also develops and provides new education seminars and training for staff throughout the year. The RD team also developed a "welcome buddy" assignment position to facilitate the integration of new hires into RD.
  Contacts: Maryam Muhammad, Lindsay Roe, FB

Peer Review for New Active Ingredients

Recurring Meeting

- RD and PRD are continuing to hold peer review meetings on new active ingredient decisions using the process developed in FY17 to improve the consistency and quality of OPP decisions.

PRIA Renegotiations - Web Forms Replacement

The Webforms / Lotus Notes renegotiation form was retired and replaced with a new tool. RD contributed to the design of the new system, and will be involved in ongoing improvements.

Inter-Divisional Initiatives

Labeling Consistency Committee

Recurring Activity

Provides interpretation and guidance for cross-cutting issues that are:

- Generic to all product labels.
- Germane to a type of pesticide (i.e., antimicrobials, insecticides, etc.).
- Relevant to a broad range of use sites.
- Related to a specific crop (that might be on many labels).
- Relevant to a class of pesticides.

LEAN: Optimizing Chemical Team Interactions

- Create more consistent, defensible, protective, and enforceable pesticide risk management decisions that are more timely and less resource-intensive.
- Leverage the timing of interactions among chemical team members and improve the quality of those interactions, such that the most appropriate risk assessment refinements and label mitigation measures are considered, and “surprises” are kept to a minimum.

Similarity Clinic Process Improvement

?A new charter is drafted and new members are in place. In FY18, RD expects to:

- Draft an SEP
- Develop system where only failed actions (not similar) are taken to similarity clinic (ask PV about this)

Pesticide Efficacy Review Committee (PERC) -- RD & BPPD Entomologists

Recurring Meetings

- The PERC will continue holding weekly meetings with minutes recorded, to:
  - Facilitate consistency across insecticide branches and serve as an internal forum for scientific discussion.
  - Provide guidance for the division. PERC serves as a resource to RD in which management and staff can bring efficacy-related questions or concerns.
  - Conduct protocol reviews and address rebuttals to PRIA actions
  - Participate in efficacy-related special projects.
  - Provide leadership and promote high scientific standards and state-of-the-art approaches to insecticide and repellent efficacy evaluations
    Contact: Dr. Jennifer Saunders

Streamlined Drinking Water Assessments

- RD worked with EFED and BEAD to implement streamlined drinking water and eco risk assessments for PRIA new uses. EFED has quantified significant resource savings from this effort.

External Facing Initiatives

New Electronic Confidential Statement of Formula (eCSF)

The workgroup consists of participants from EPA and representatives from the registrant community. This workgroup is working with software developers to develop a new electronic Confidential Statement of Formula (eCSF) form that will allow registrants to submit product specification data electronically. Eventually, this system will be an integral part of OPPs vision to move towards a secure, searchable, electronic data base to house active and retired CSFs. RD's role is to help define all the parameters, definitions and ensure all the requirements have been adequately addressed.

- Completed software development for testing
- Pilot testing started in FY19
  Contacts: Marianne Lewis, Venus Eagle, IVB3.

OPP E-Label (formerly "SmartLabel" (OPP Team lead by RD)

In an effort to make pesticide label information easier to find and the approval of pesticide labels more efficient, EPA is working with pesticide registrants to pilot an electronic label system, SmartLabel.

- A label builder for registrants was completed for pilot testing, as well as a review tool for OPP label reviewers
- High level training provided for internal and external stakeholders
- A pilot for registrants to submit and OPP to review E-Labels, and other work, is underway in FY19
  RD Contact: Baris Reuben

Web Distributed Labeling (RD, OPP)

Ongoing Effort

- RD contributes to the Web Distributed Labelling pilot. The WDL group is forming a strategy to allow for quicker access to the most up-to-date labels for users, distributed on controlled company websites.

APPENDIX A: NEW ACTIVE COMPLETIONS

APPENDIX B: NEW USES